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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,266	LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-84* is/are pending in the application.

4a) Of the above claim(s) *68 and 69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-67 and 70-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 48-67 and Claims 70-84 in the reply filed on April 12, 2004 is acknowledged. The traversal is on the ground that it would not be a serious burden for the Examine to search Groups I and II, since Applicant deems that the search and examination of Groups I and II would be co-extensive. Applicant further argues that the search for the claim-designated cosmetic/pharmaceutical composition "would likely uncover references that also disclose the use of such an admixture in a regime or regimen for promoting hair growth and/or retarding hair loss, for increasing the mean diameter of strands of hair and/or decreasing the heterogeneity thereof, and/or for increasing hair density, and/or improving the quality and/or appearance of a head of hair, and/or inducing repigmentation of the hair. This is not found persuasive for the reasons set forth in the previous Office action dated March 16, 2004. For instance, the process for using the product as claimed can be practiced with another materially different product, as evidenced by the teachings Galey et al. in US 6156899, Nelson in US 6149933, Buultjens in US 5068315, and Mesquitta in US 5827510.

Contrary to Applicant's arguments, the inventions are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search.

Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case, as the claimed regimens for the use of the claim-designated composition are directed to a method of promoting hair growth versus a method of increasing the mean diameter of hair strands versus improving the quality or the appearance of a hair versus a method for inducing repigmentation of the hair. Thus, it would be an undue burden to examine all of the above inventions in one application.

Applicant further requests withdrawal of the restriction requirement "Because process Claims 68 and 69 include all of the elements of elected product Claims 48 and 58, process Claims 68 and 69 must be rejoined with the product claims once the product claims are found to be allowable." Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), process claims which depend from or otherwise include all of the limitations of the allowable product will be rejoined and fully examined for patentablility under 37 CFR 1.104, at the time a product claim is found allowable. However, no product claim has been found allowable, in the instant case.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 48-67 and 70-84 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-67 and 70-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 48, 58 and 70-84 are rendered uncertain by the phrase "are the only active agents in the composition" because while the preamble of the claims direct the subject matter of the invention to a cosmetic/pharmaceutical composition comprising an admixture of claim-designated ingredients, the body of the claims does not recite an intended use of the claimed cosmetic/pharmaceutical composition. The lack of clarity renders the claim vague and indefinite. Accordingly, it is suggested that the phrase --for treating hair loss-- after the term "composition" in line 1, and the phrase --an effective amount of-- be inserted after the word "comprising" (line 1) or, alternatively, that the limitations recited in independent Claims claim 4 (and all relevant intervening claims) be appropriately incorporated into claim 1, to clarify this ambiguity.

Claims 48-67 and 70-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
The metes and bounds of Claim 48, 58 and 70-84 are rendered uncertain by the phrase "are the only active agents in the composition" because while the preamble of the claims direct the subject matter of the invention to a

cosmetic/pharmaceutical composition comprising an admixture of claim-designated ingredients, the body of the claims does not recite an intended use of the claimed cosmetic/pharmaceutical composition. Thus, the lack of clarity renders the claim vague and indefinite. Accordingly, it is suggested that the phrase --for treating hair loss-- after the term "composition" in line 1, and the phrase --an effective amount of-- be inserted after the word "comprising" (line 1) or, alternatively, that the limitations recited in independent Claims 81 and 82 (and all relevant and/or intervening claims) be appropriately incorporated into the claims, to clarify this ambiguity.

Although not rising to the level of certainty, it is apparent that an article was omitted from the claim language of Claims 53 and 63, line 4. Applicant may overcome the rejection by adding a before "combination".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 51, 57, 81 and 83 rejected under 35 U.S.C. 102(a) as being anticipated by DE 29916231 U1 (N).

Applicant claims a cosmetic/pharmaceutical composition comprising an admixture of vitamin A, vitamin C, vitamin E, zinc and selenium, in the form of selenite, selenocysteine or selenoyeast, are the only active agents in the compositon. Applicant further claims compositions having claimed dose amounts of ingredients.

DE 29916231 teaches a multivitamin and mineral composition comprising 100-200 mg vitamin C (as calcium ascorbate), 70-130 mg vitamin E (DL- alpha - tocopherol acetate), 20-80 mg vitamin B1 (thiamine hydrochloride), 20-80 mg vitamin B2 (riboflavin), 20-80 mg vitamin B3 (nicotinamide), 20-80 mg vitamin B5 (as calcium pantothenate), 20-80 mg vitamin B6 (pyridoxine hydrochloride), 0.08-0.15 mg vitamin B12 (cyanocobalamin), 20-80 mg inositol, 0.3-0.5 mg folic acid, 0.03-0.08 mg biotin, 300-500 IU vitamin D3 (cholecalciferol), 1000-5000 IU vitamin A (retinol palmitate), 70-150 mg calcium hydrogen sulfate, 30-80 mg magnesium oxide, 25-40 mg iron (II) sulfate, 12-18 mg zinc sulfate, 0-3 mg manganese (II) sulfate, 0-3 mg copper sulfate, 160 mu g sodium molybdate, 0.08-0.12 mg potassium iodide and 30-50 mg selenium yeast.

It is also that the composition disclosed in the cited prior art contains numerous ingredients in addition to the instantly claimed ingredients in Applicant's claims. However, since the preamble of the claims fail to recited an

intended use for the instantly claimed cosmetic/pharmaceutical composition it is uncertain whether the additional ingredients taught in the prior art reference are active agents or whether the additional ingredients in the prior art product materially would affect the basic novel properties of the claimed invention, as set forth in the rejection made under 35 USC 112, second paragraph set forth immediately above.

The reference anticipates the claimed subject matter.

Claim 78 is rejected under 35 U.S.C. 102(b) as being anticipated by Drug Launch (U).

Applicant claims a cosmetic/pharmaceutical composition comprising an admixture comprising about 0.1 mg to about 3 mg of vitamin A, about 50 mg to about 240 mg of vitamin C, about 10 mg to about 60 mg of vitamin E, about 10 mg to about 40 mg of zinc and about 70 μg to about 120 μg of selenium, wherein the composition is formulated for oral administration.

Applicant argues that the cited prior reference fails to anticipate the instantly claimed subject matter because the Bausch & Lomb facsimile does not constitute a proper "printed publication" under §2128; and that neither Drug Launches nor the Bausch & Lomb facsimile teaches each element of the claims at issue. However, Applicant's invention is not persuasive because Drug Launches teaches OCUVITE™, which comprises zinc oxide (40 mg), copper oxide (2 mg), vitamin C (60 mg), vitamin E (30 IU or 30 mg), vitamin A

(as beta-carotene, 5000 IU or 3 mg), and selenium (40 mcg) in combination with a pharmaceutically acceptable carrier in the making of tabs for oral administration; and, the Bausch & Lomb facsimile was only relied upon to provide evidence of an inherent feature of the cited reference, namely that the vitamin comprising OCUVITE™ was in the form of beta-carotene.

It is noted that the composition disclosed in the cited prior art contains numerous ingredients in addition to the instantly claimed ingredients in Applicant's claims. However, since the preamble of the claims fail to recited an intended use for the instantly claimed cosmetic/pharmaceutical composition it is uncertain whether the additional ingredients taught in the prior art reference are active agents or whether the additional ingredients in the prior art product materially would affect the basic novel properties of the claimed invention, as set forth in the rejection made under 35 USC 112, second paragraph set forth immediately above.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 48, 49, 51, 52, 55-59, 61, 62, 65-67, 70, 72-77, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launch (U) in view of Crary (B) .

Applicant claims a cosmetic/pharmaceutical composition comprising an admixture of vitamin A, vitamin C, vitamin E, zinc and selenium, in the form of selenite, selenocysteine or selenoyeast, are the only active agents in the compositon. Applicant further claims compositions having claimed dose amounts of ingredients. Applicant further claims compositions formulated as a drinkable solution, syrup, tablets, or capsules.

Drug Launches teaches OCUVITE™, which comprises zinc oxide (40 mg), copper oxide (2 mg), vitamin C (60 mg), vitamin E (30 IU or 30 mg), vitamin A (as beta-carotene, 5000 IU or 3 mg), and selenium (40 mcg) in combination with a pharmaceutically acceptable carrier in the making of tabs for oral administration.

The teachings of Drug Launches are set forth above. Drug Launches teaches the claimed invention except for wherein the selenium is in the form of selenite, selenocysteine or selenoyeast. However, it would have been obvious to one of ordinary skill in the art to modify the composition taught by Drug Launches to provide the instantly claimed composition because at the time the invention was Crary teaches a composition comprising 250 and 1000 mcg of sodium selenite and vitamin E which is used in a method of treating and preventing macular edema of diabetic retinopathy. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a

reasonable expectation of success to replace the selenium taught by Drug Launches the sodium selenite composition taught by Crary because Crary teaches that an admixture of therapeutic effective amounts of vitamin E and sodium selenite, as well as seleononthianone or selenium yeast, has the beneficial functional effect to stop complications of capillary leakage and bleeding in diabetic patients suffering retinopathy, in Column 3, lines 3-12. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 48, 49, 51-53 55-59, 61-63, 65-67, 70, 72-77, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launch (U) and Crary (B) in view of Magistretti et al. (C).

Applicant's claimed invention of Claims 48, 49, 51, 52, 55-59, 61, 62, 65-67, 70, 72-77 and 79 was set forth above. Applicant further claims the cosmetic/pharmaceutical composition as defined by either claim 48 or claim 58, further comprising an additional antioxidant, a catalase, a peroxidase, a synthetic molecule exhibiting enzymatic activity which mimics a peroxidase, a sulfur-containing amino acid, or a combination thereof.

The combined teachings of Drug Launch and Crary are set forth above. Drug Launch and Crary teach the instantly claimed cosmetic/pharmaceutical composition except for an additional antioxidant. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional antioxidant to the cosmetic/pharmaceutical composition taught by the combined teachings of Drug Launch and Crary to provide the instantly claimed invention because Magistretti teaches an antioxidant pharmaceutical composition comprising anthocyanidins, *i.e,,* pelargonidin and delphidin, are useful in the making of ophthalmic compositions for oral or local administration. At the time the invention was made, one of ordinary skill in the art would have motivated and one would have had a reasonable expectation of success to add the antioxidant-containing composition taught by Magistretti to the cosmetic/pharmaceutical composition taught by the combined teachings of Drug Launch and Crary to provide the instantly claimed composition because Magistretti teaches that the reference composition reduce the permeability of ciliary body vessels involved in the regulation of endo-ocular pressure and of the blood water barrier, and in the production of aqueous humor. Moreover, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 48-50, 54, 58-60, 48-50, 54, 58-60, 64, 71, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (O), Takasu et al. (D), Bazzano (E), Schardt (Q) and Okada (P).

Applicant's claimed invention of Claims 48, 49, 58 and 59 was set forth above. Applicant further claims compositions having claimed dose amounts of ingredients. Applicant claims a cosmetic/pharmaceutical composition comprising an admixture of vitamin A, vitamin C, vitamin E, zinc and selenium, in the form of selenite, selenocysteine or selenoyeast, wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition and wherein

the composition is a topical anti-hair loss composition. Applicant claims a cosmetic/pharmaceutical composition comprising an admixture of vitamin A, vitamin C, vitamin E, zinc and selenium, in the form of selenite, selenocysteine or selenoyeast, wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the compositon and wherein the composition is a topical anti-hair loss composition and wherein the selenium is present in an amount between about 70 μg and 120 μg.

Davis teaches a hair care composition comprising at least 1000 lug^{-1} of Vitamin A (retinol) in a topically acceptable carrier, which is useful for increasing the diameter of growing hair. Bazzano teaches a composition comprising retinoic acid (vitamin A) for either oral or topical administration, which is useful in increasing the rate of hair growth, stimulating hair follicules to produce new hair growth, prolonging the anagen phase of the hair cycle, and treating alopecias. Takasu teaches topical hair care compositions comprising as an active agent a phosphoric acid with ascorbic acid (vitamin C) and tocopherol (vitamin E), which is useful in the treatment of hair loss. Schardt teaches an aqueous hair lotion for controlling dandruff and alopecia, containing lactic acid, citric acid, (dex)panthenol, sodium selenite, zinc sulfate and optionally potassium iodate, silicic acid and ascorbic acid. Okada teaches a hair cosmetic suppressing yellowing of hair blending a hair cosmetic with preferably 0.0001-1.0wt.% selenium compound, e.g. organoselenium compound such selenomethionine, selenocysteine or selenocystine or inorganic selenium compound such as sodium selenite. he cosmetic is further used with 0.0001-1.0wt.% flavonoid

(flavonoid as it is or apigenin, luteolin or quercetin prepared by processing flavonoid) to further improve yellowing suppressing effects.

Each of the teachings of over Davis, Takasu, Bazzano, Schardt, and Okada teach a cosmetic/pharmaceutical composition comprising an ingredient that is useful in the making of an anti-hair loss topical hair composition. None of Davis, Takasu, Bazzano, Schardt and Okada teaches a cosmetic/pharmaceutical composition comprising each of the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art, and would have been motivated and one would have had a reasonable expectation of success to combine the ingredients taught by Davis, Takasu, Bazzano, Schardt, and Okada to provide the instantly claimed invention because each of the above-cited references teach that vitamin A, vitamin C, vitamin E, zinc and selenium are useful in the making of cosmetic/pharmaceutical compositions having the beneficial function of promoting hair growth or retarding hair loss. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169

USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
June 28, 2004